REMARKS/ARGUMENTS

The Invention

The invention pertains to a composition comprising an interluekin-2 receptor associated polypeptide, wherein the polypeptide is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82, and methods of purifying the same.

The Pending Claims

Upon entry of this amendment, claims 1, 3-5, 9, 11-15, and 22-25 will be pending. Claims 1, 3-5, and 22-25 are directed to compositions comprising interleukin-2 receptor associated polypeptides, which are capable of forming a complex with monoclonal antibodies produced by the hybridoma PTA-82. Claims 9 and 11-15 are directed to methods of purifying the subject interleukin-2 receptor associated polypeptides.

The Amendments to the Claims

Claims 1 and 3 have been amended to recite that the interleukin-2 receptor associated polypeptide is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82. These amendments are supported by the specification at, for example, page 26, line 7-page 27, line 23. Claim 9 has been amended to recite that the method comprises providing cells expressing an interleukin-2 receptor and an interleukin-2 receptor associated polypeptide, and solubilizing the cells to produce a cell extract. The amendments to claim 9 are supported by the specification at, for example, page 35, line 23-page 36, line 2, and by original claim 10. Claim 13 has been amended to correct typographical errors. Claim 10 has been cancelled. Claim 11 has been amended to change the claim dependency as a result of the cancellation of claim 10. Claims 24 and 25 are new and are supported by the specification at, for example, page 26, line 7-page 27, line 23, and page 39, lines 9-28. Accordingly, no new matter has been added by way of these amendments.

The Office Action

Claim 13 is objected to for containing a typographical error. Claims 1, 3-5, 9-15, 22, and 23 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Claims 1, 3-5, 9, 10, 13-15, 22, and 23 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over Colamonici et al., *J. Immunol.*, *145*, 155-160 (1990) ("the Colamonici reference"). The claims have been amended to place the application in condition for allowance or in better form for an appeal. Accordingly, reconsideration of these rejections is respectfully requested, and entry of the amendment is earnestly solicited.

Discussion of the Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office Action contends that the metes and bounds of claims 1 and 3 cannot be determined because the structures of the polypeptides in the claimed composition are unclear. In particular, the Office Action alleges that different polypeptides can have the same molecular weight and share epitopes.

The Office Action maintains that the term "reactive" in claims 1 and 3 is unclear. Solely in an effort to advance prosecution of the subject application, and not in acquiescence of the rejection, claims 1 and 3 have been amended to recite that the interleukin-2 receptor associated polypeptide is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82. One of ordinary skill in the art would understand that a polypeptide is capable of forming a complex with an antibody when the polypeptide recognizes and interacts with the antibody.

Claims 1 and 3, as amended, are directed to an interleukin-2 receptor associated polypeptide that is defined not only by its molecular weight, but also by its ability to form a complex with the monoclonal antibody produced by the hybridoma PTA-82. It is well established that a monoclonal antibody is a single type of antibody molecule directed against a single specific epitope on a preselected antigen (see, e.g., Janeway et al., eds., *Immunobiology*, 5th edition, Garland Publishing, New York, NY (2001)). Due to that specificity, any polypeptide which is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82 and has a molecular weight of about 32,000 to 34,000 daltons or about 26,000 to 28,000 daltons *is* an interleukin-2 receptor associated polypeptide as defined by the pending claims. Thus, while claims 1 and 3 encompass *any* such polypeptide, the polypeptides that meet these criteria are clearly defined, and one of ordinary skill in the art would understand the metes and bounds of these amended claims.

The Office Action maintains that claim 9 is incomplete because it omits essential elements. Solely in an effort to advance prosecution of the subject application, and not in acquiescence of the rejection, claim 9 has been amended to include the steps of (a) providing cells expressing an interleukin-2 receptor and an interleukin-2 receptor associated polypeptide, (b) solubilizing the cells to produce a cell extract, and (c) contacting the cell extract with an anti-interleukin-2 receptor associated polypeptide antibody. Claim 10 is said to be indefinite because it is allegedly impossible to contact cells with an antibody after the cells have been solubilized. The rejection of claim 10 has been rendered moot by the amendment of claim 9 and the cancellation of claim 10.

In view of the foregoing, Applicants submit that claims 1, 3-5, 9, 11-15, and 22-25 particularly point out and distinctly claim the present invention. Therefore, Applicants respectfully request that the rejection of claims 1, 3-5, 9, 11-15, 22, and 23 under Section 112, second paragraph, be withdrawn.

Discussion of Rejection Under 35 U.S.C. §§ 102(b)/103(a)

Claims 1, 3-5, 9, 10, 13-15, 22, and 23 are rejected under Section 102(b) as allegedly anticipated by, or in the alternative, under Section 103(a) as allegedly obvious in view of, the Colamonici reference. This rejection is traversed for the reasons set forth below.

As a preliminary matter, Applicants submit that the Section 102(b)/103(a) rejection is being used as a substitute for a rejection under Section 102, which is improper (M.P.E.P. § 706.02(m)). The Office should have made a single rejection under either Section 102 or Section 103, as such a rejection is possible given that the claims in dispute are ascertainable. Applicants respectfully submit that the rejection under Section 102/Section 103 is improper and should be withdrawn.

Despite the improper rejection, according to the Office Action, the Colamonici reference discloses polypeptides having molecular weights of *about* 32-34 kDa (i.e., 37 kDa), and *about* 26 kDa-28 kDa (i.e., 20 kDa), which associate with a subunit of the IL-2 receptor.

The Colamonici reference specifically discloses IL-2 receptor associated polypeptides of 37 kDa and 20 kDa, which were immunoprecipitated from HUT-102 cells and MT-1 cells with the monoclonal antibodies anti-Tac and 7G7/B6 (see Colamonici reference at page 159, second column). Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 executed by Thomas A. Waldmann, M.D., which declares that the 32-34 kDa and 26-28 kDa polypeptides of the pending claims are present in lysates from cells recognized by the anti-Tac monoclonal antibody that have been pre-cleared with anti-Tac. The declaration further describes a cell line that is capable of forming a complex with the 5F7 monoclonal antibody (i.e., the monoclonal antibody produced by the hybridoma PTA-82), but cannot form a complex with either anti-Tac or 7G7/B6, as this cell line does not express the CD25 antigen (also known as IL-2R alpha). These data strongly suggest that the 37 kDa and 20 kDa polypeptides described in Colamonici et al. are not capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82, as required by the pending claims. Accordingly, the IL-2 receptor associated polypeptides disclosed in the Colamonici reference are not the same as the IL-2 receptor associated polypeptides that are claimed.

Moreover, the advanced level of skill in the art is such that a person of ordinary skill in the art would not consider a 37 kDa protein to be a polypeptide having a molecular weight of *about* 32-34 kDa, as recited in claim 1. Indeed, the difference in size between the 37 kDa protein of the Colamonici reference and the polypeptide of claim 1 is between about 5,000 daltons and 3,000 daltons. Such a size difference is significant, and one of ordinary skill in the art would recognize that the 37 kDa protein is distinct from the presently claimed polypeptides. Likewise, the size difference between the 20 kDa protein of the Colamonici reference and the polypeptide of claim 3 is even greater than the size difference between the

37 kDa polypeptide of the Colamonici reference and the polypeptide of claim 1 of the subject application. Thus, the Colamonici reference does not disclose the subject matter of the pending claims. See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985), which holds that, in order to anticipate claims defined by a particular range, the claimed subject matter must be disclosed in the reference with sufficient specificity to constitute anticipation. See also *Ex parte Lee*, 31 U.S.P.Q. 2d. 1105 (Bd. Pat. App. & Inter. 1993) (expanded Board), which holds that anticipation under Section 102 can be found only when a reference discloses *exactly* what is claimed. The difference in properties between the polypeptides disclosed in the Colamonici reference and the polypeptides claimed in the subject application, namely that the polypeptides of the present invention form a complex with the monoclonal antibody produced by the hybridoma PTA-82, whereas the polypeptides of the Colamonici reference do not, underscores the fact that the polypeptides are not the same.

The Colamonici reference also does not render obvious the subject matter of the pending claims. As discussed above, the Colamonici reference does not disclose or suggest an IL-2 receptor associated protein that is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82, and it does not disclose an IL-2 receptor associated polypeptide that is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82 and having a molecular weight of about 32-34 kDa or about 26-28 kDa. In view of these deficiencies of the Colamonici reference, it is not apparent how one of ordinary skill in the art could modify the disclosure of the Colamonici reference in a way so as to arrive at the presently claimed invention.

For the foregoing reasons, the Office Action fails to establish the criteria for a proper anticipation rejection, or a *prima facie* case of obviousness, and the Section 102/103 rejection should be withdrawn.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

Bruce M. Gagala, Reg. No. 28,844
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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